

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT

Applicant: Richard L. Scopp, et al.

Group Art Unit: 1641

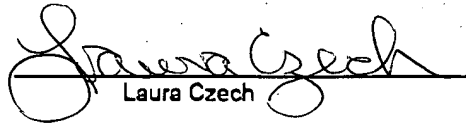
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For: METHODS AND KITS FOR DECREASING INTERFERENCES IN PLASMA OR SERUM CONTAINING ASSAY SAMPLES OF SPECIFIC BINDING ASSAYS


Laura Czech

Attorney Docket No.: 6734.US.01

Examiner: Pensee T. Do

**DECLARATION OF RICHARD L. SCOPP UNDER
37 C.F.R. 1.132**

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

I, Richard L. Scopp, declare:

1. I received my B.S. in biology from North Central College in Naperville, Illinois and my M.S. in biochemistry from the Medical College of Wisconsin, Milwaukee, Wisconsin. I have been employed by Abbott Laboratories ("Abbott"), the assignee of the above-identified patent application for the last fifteen (15) years. During my employment with Abbott, I have conducted research in the area of immunoassay development.

2. I am one of the inventors of the above-identified patent application.

3. In the Office Action mailed on October 5, 2005, the Examiner rejected claims 1, 2, 4-17 and 26 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner alleges that the claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In addition, the Examiner also argues that with respect to the TSH assay described in the Examples that the polyclonal could be conjugated to other molecules such as BSA for blocking non-specific binding on a solid phase. The Examiner also says that BSA is well known to those skilled in the art and is often not mentioned if it is being used.

4. The claimed invention relates to methods of decreasing interferences in specific binding assays. Specifically, the invention is based on the discovery that the addition of an effective amount of a large, unconjugated polycation in a serum or plasma assay is capable of decreasing interferences in said assays which typically result in inaccurate readings. More specifically, the polycation is simply included in the specific binding assay as an additive, such as part of the diluent. When the polycation is added to the assay as recited in the claims, it has not been conjugated to any other molecule.

5. Although the specification does not expressly recite the word "unconjugated", it would be readily apparent to anyone skilled in the art, such as myself, that this term is inherently disclosed in the specification, particularly at pages 2-4, 6 and Examples 2-4 of the specification.

6. As mentioned previously herein, the polycation used in the methods of the claimed invention is unconjugated. The specification on page 6, lines 11-22 provides examples of the amount and types of polycations that can be used in the claimed methods. No mention of conjugation to other molecules is described.

In Example 2, lines 14-17, the specification states "[I]n separate experiments, a polycation, i.e., polylysine, polybrene or MERQUAT, then was added to the TSH Assay Diluent and combined with the serum or plasma sample (150 μ L) and anti- β TSH antibody coated paramagnetic microparticles (50 μ L at 0.1% solids) in the first step of the TSH assay" (emphasis added). Contrary to the Examiner statements, had BSA been conjugated to a polycation, a description of the conjugation reaction and the resulting conjugate would have been provided. The purpose of such a conjugate would have also been described.

In Example 3, lines 26-28 the specification states, "[I]n these experiments, a polycation, in particular, a poly-amino acid, was substituted in place of dextran sulfate in the microparticle diluent. The assay then was performed as described in the general procedure above."

There is nothing in Examples 2 and 3 to suggest that the polycations added to assay samples are conjugated. If these polycations were conjugated to one or more other molecules, these molecules would be identified as being included in the immunoassay and the method of their preparation would be explicitly described. Moreover, their function in the immunoassay would also be identified. In fact, when describing a molecule designed to reduce interference in a method of reducing interferences, one skilled in the art, such as myself, would not fail to describe any other molecules that are conjugated to the interference-reducing molecule, nor would one skilled in the art expect others in the field to neglect to include such a description. Thereupon, those skilled in the art would immediately and clearly understand that the polycations described in the above-identified application do not contain any other molecules conjugated to them.

7. I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



Richard L. Scopp

4/4/2006

Date